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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,578	02/12/2004	Paul O. Sheppard	01-26C1	5427

7590

10/10/2006

Robyn Adams  
Patent Department  
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1201 Eastlake Avenue East  
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EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/777,578

Applicant(s)

SHEPPARD ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2 & 7, drawn to the novel secreted polypeptide of SEQ ID NO: 2, classified in class 530, subclass 350.
  - II. Claims 3-6 & 8, drawn to polynucleotides encoding the novel secreted polypeptide of SEQ ID NO: 2, vectors, host cells, and methods of making the protein recombinantly, classified in class 435, subclass 69.1.
  - III. Claim 9, drawn to antibodies directed against the novel secreted polypeptide of SEQ ID NO: 2, classified in Class 530, subclass 387.1.
  - IV. Claims 10-11 & 16, drawn to the novel secreted polypeptide of SEQ ID NO: 5, classified in class 530, subclass 350.
  - V. Claims 12-15 & 17, drawn to polynucleotides encoding the novel secreted polypeptide of SEQ ID NO: 5, vectors, host cells, and methods of making the protein recombinantly, classified in class 435, subclass 69.1.
  - VI. Claim 18, drawn to antibodies directed against the novel secreted polypeptide of SEQ ID NO: 5, classified in Class 530, subclass 387.1.
  - VII. Claims 19-20 & 25, drawn to the novel secreted polypeptide of SEQ ID NO: 8, classified in class 530, subclass 350.
  - VIII. Claims 21-24 & 26, drawn to polynucleotides encoding the novel secreted polypeptide of SEQ ID NO: 8, vectors, host cells, and methods of making the protein recombinantly, classified in class 435, subclass 69.1.

IX. Claim 27, drawn to antibodies directed against the novel secreted polypeptide of SEQ ID NO: 2, classified in Class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-IX are directed to products that are physically and functionally distinct involving proteins, nucleic acids, and antibodies. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Groups I, IV and VII are fundamentally different molecules than the nucleic acid molecules of Groups II, V and VIII, which in turn can be used to clone proteins, detect cells that express the protein, or used as therapeutic agents in gene therapy. In contrast, the proteins of Groups I, IV and VII can be utilized in making antibodies or used in affinity chromatography or used as a different class of therapeutic agents. Although the antibodies of Groups III, VI and IX can be used in isolating the proteins of Groups I, IV and VII, respectively, the antibodies of Group III, VI and IX can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in immuno-assays, or as therapeutic agents themselves. Nevertheless, the proteins of Groups I, IV and VII can be utilized in making the antibodies of Groups III, VI and IX, but not vice versa. Lastly, the proteins of Groups I, IV and

Art Unit: 1649.

VII, the nucleic acids that encode such of Groups II, V and VIII, and the antibodies of Groups III, VI and IX are structurally and functionally distinct as illustrated by their unique SEQ ID NOs, or the unique epitopes to which they bind, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

Art Unit: 1649

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'RCH', is positioned above the printed name of the examiner.

Robert C. Hayes, Ph.D.  
September 29, 2006

ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER